AUG 19 2011

K102706
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510(k) Summary

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Contact Person	Fabio Rota Technical Director +39 02 34551448 Fax: +39 02 34551464
Date of Preparation of this Summary:	August 18th, 2011
Trade Name:	CKMB UDR Assay
Classification Name:	Creatine phosphokinase/creatine kinase or isoenzymes test system.
Device Classification product code Subsequent Product Code	JHW / JIX
Regulation number/Class	862.1215 / Class II

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The assigned 510(k) number is: __K102706.

Test Description:

Anti CK-M mouse monoclonal antibodies in the reagent 1 inhibit the CK-M subunit in the sample without affecting the CK-B subunits. The CK-B activity is determined by the CK-NAC method and corresponds to half the CK-MB activity.

Substantial Equivalence:

The CKMB UDR assay is substantially equivalent to Roche CK-MB assay (K003158). Both assays yield similar Performance Characteristics.

Similarities:

- Both assays are used for the quantitative determination of CKMB
- Both assays are based on immunologic inhibition of the CK-M subunit of Human Creatine kinase
- Both assays are based on the same Immunological key materials: anti CK-M mouse monoclonal antibodies, which are bought from Roche.
- Both assays are based on the Kinetic measurement of the CK-B subunit of the human Creatine Kinase
- Both assays do have 340 nm as main wavelength
- Both assays utilize reagents in R1 and R2 Liquid format.
- Both assays are based on human Serum and Li-heparin Plasma.
- Both assays yield similar clinical results.

Differences:

- The predicate device assay recommends the use of EDTA plasma specimens. Sentinel assay recommends the use of serum and Li-Heparin plasma only.

Intended Use:

The CKMB UDR assay is an *in vitro* diagnostic test used for the kinetic quantitative determination on Unicel DxC 600 System of the CK-MB isoenzyme activity of creatine kinase in serum and Liheparin plasma by inhibition method. The assay is intended for professional use only.

Performance Characteristics:

Comparative performance studies were conducted using the UniCel DxC 600 Synchron System. Sentinel CKMB UDR assay on UniCel DxC 600 System yielded comparable performances to the Roche CK-MB (K003158) on Roche/Hitachi Modular P800 Analyzer (K953239/A5).

Method comparison

Sentinel CKMB UDR assay on UniCel DxC 600 System was compared to predicate device Roche CK-MB (K003158) on Roche/Hitachi Modular P800 by testing 306 human sera samples. This comparison showed a correlation coefficient (r) of 0.999, slope of 0.96, and intercept of 2.40 U/L.

Conclusions

The generated data demonstrated an acceptable correlation between the CKMB UDR assay on the UniCel DxC 600 System vs. the Roche CKMB (K003158) on Roche/Hitachi Modular P800 Analyzer.

Imprecision

Precision studies were conducted by using CKMB UDR on the UniCel DxC 600 System. The found %CV values for 20-day Inter-assay Imprecision were:

	N	Mean (U/L)	Total Imprecision		Within run	
			SD (U/L)	CV%	SD (U/L)	CV%
Human sera pool #1	40	10.7	0.45	4.2	0.45	4.2
Human sera pool #2	40	19.0	0.49	2.6	0.49	2.6
Human sera pool #3	40	25.4	0.50	2.0	0.50	2.0
Human sera pool #4	40	33.4	1.21	3.6	1.21	3.6
Spiked Human sera pool	40	584.1	5.11	0.9	3.76	0.6

Analytical Measurement Range (AMR)

The found lower limit of the AMR of CKMB UDR on the UniCel DxC 600 System was 7.4 U/L. The found upper limit of the AMR was 600.0 U/L. The claimed AMR will be 9.0 to 600.0 U/L.

Conclusions for 510(k) Summary

Method comparison, Imprecision and AMR data demonstrate that the analytical performance of the CKMB UDR on the UniCel DxC 600 Synchron System is substantially equivalent to Roche CK-MB (K003158) on the Roche/Hitachi Modular P800 Analyzer

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

SENTINEL CH SpA
c/o Fabio Rota
Via Robert Koch
20152
Milan, Italy

AUG 19 2011

Re: k102706
Trade/Device Name: CKMB UDR Assay
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system.
Regulatory Class: Class II
Product Code: JHS
Dated: August 10, 2011
Received: August 12, 2011

Dear Mr. Rota:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _K102706_____

Device Name: CKMB UDR

Indications for Use:

The CKMB UDR assay is an *in vitro* diagnostic test used for the kinetic quantitative determination on Unicel DxC 600 System of the CK-MB isoenzyme activity of creatine kinase in serum and Li-heparin plasma by inhibition method. The assay is intended for professional use only. Creatine Kinase (CK) catalyses the reversible phosphorylation of creatine by ATP. CK is a dimer composed of two subunits which form three active isoenzymes: BB (CK-1), MB (CK-2), MM (CK-3). CK-BB isoenzyme only rarely appears in serum.

Elevated CK values are due to muscular damages and associated pathologies. CK determination, usually performed with CK2 (also called CK-MB), is used for the diagnosis and follow-up of AMI (acute myocardial infarction) and some muscular diseases.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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